BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: James Jamshid Elist, **M.D.** Physician's and Surgeon's Certificate No. A 35400 Respondent.	MBC File # 800-2018-048274

ORDER CORRECTING NUNC PRO TUNC CLERICAL ERROR IN "CHAIRPERSON'S NAME" PORTION OF DECISION

On its own motion, the Medical Board of California (hereafter "Board") finds that there is a clerical error in the "chairperson's name" portion of the Decision in the above-entitled matter and that such clerical error should be corrected to indicate that Randy W. Hawkins, M.D. presided over this meeting.

IT IS HEREBY ORDERED that the chairperson's name "Laurie Rose Lubiano, J.D." contained on the Decision Order Page in the above-entitled matter be and hereby is amended and corrected nunc pro tunc as of the date of entry of the decision to read as "Randy W. Hawkins, M.D."

June 6, 2024

Randy W. Hawkins, M.D., Vice Chair,
Panel A

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: James Jamshid Elist, M.D. Physician's and Surgeon's Certificate No. A 35400 Respondent.	Case No.: 800-2018-048274

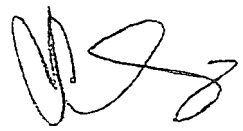
DECISION

The attached Stipulated Settlement and Disciplinary Order is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on June 28, 2024.

IT IS SO ORDERED: May 29, 2024.

MEDICAL BOARD OF CALIFORNIA



Laurie Rose Lubiano, J.D., Chair
Panel A

ROB BONTA
Attorney General of California
ROBERT MCKIM BELL
Supervising Deputy Attorney General
VLADIMIR SHALKEVICH
Deputy Attorney General
State Bar No. 173955
300 South Spring Street, Suite 1702
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Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: JAMES JAMSHID ELIST, M.D. 8500 Wilshire Boulevard, Suite 707 Beverly Hills, California 90211 Physician's and Surgeon's Certificate A 35400, Respondent.	Case No. 800-2018-048274 OAH No. 2021120299 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Reji Varghese (Complainant) is the Executive Director of the Medical Board of California (Board). He brought this action solely in his official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Vladimir Shalkevich, Deputy Attorney General.

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2. Respondent James Jamshid Elist, M.D. (Respondent) is represented in this proceeding by attorney Peter R. Osinoff and Derek O'Reilly-Jones of Bonne, Bridges, O'Keefe & Nichols, 355 South Grand Avenue, Suite 1750, Los Angeles, California 90071.

3. On June 23, 1980, the Board issued Physician's and Surgeon's Certificate No. A 35400 to James Jamshid Elist, M.D. (Respondent). That license was in full force and effect at all times relevant to the charges brought in Accusation No. 800-2018-048274, and will expire on June 30, 2024, unless renewed.

JURISDICTION

4. A Sixth Amended Accusation in Case No. 800-2018-048274 was filed before the Board, and is currently pending against Respondent. The original Accusation in this matter, and all other statutorily required documents, were properly served on Respondent on or about September 15, 2021. The Sixth Amended Accusation was served on him on August 4, 2023. Respondent filed a timely Notice of Defense contesting the charges.

5. A copy of the Sixth Amended Accusation in Case No. 800-2018-048274 is attached as Exhibit A and is incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Sixth Amended Accusation in Case No. 800-2018-048274. Respondent has also carefully read, fully discussed with his counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in the Sixth Amended Accusation No. 800-2018-048274, if proven at a hearing, constitute cause for imposing discipline upon his Physician's and Surgeon's Certificate.

10. Respondent does not contest that, at an administrative hearing, complainant could establish a prima facie case with respect to the charges and allegations in the Sixth Amended Accusation No. 800-2018-048274, a true and correct copy of which is attached hereto as Exhibit A. Respondent hereby gives up his right to contest those charges, and he has thereby subjected his Physician's and Surgeon's Certificate, No. A 35400 to disciplinary action.

11. Respondent agrees that his Physician's and Surgeon's Certificate is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Medical Board of California. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. Respondent agrees that he may file a petition for early termination or modification of probation two years after the effective date of the Decision in this case, but the effective date of any decision on Respondent's penalty relief petition shall not be sooner than three years after the effective date of this Decision. Respondent agrees that if he ever petitions for early termination or modification of probation, or if an accusation and/or petition to revoke probation is filed

against him before the Board, all of the charges and allegations contained in the Sixth Amended Accusation No. 800-2018-048274 shall be deemed true, correct and fully admitted by respondent for purposes of any such proceeding or any other licensing proceeding involving Respondent in the State of California.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or opportunity to be heard by the Respondent, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED THAT Physician's and Surgeon's Certificate No. A 35400 issued to Respondent James Jamshid Elist, M.D. is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. LIMITATION ON THE NUMBER OF SURGICAL PROCEDURES. In order to ensure that Respondent is available to his patients to address their post-surgical needs and to provide adequate informed consent, Respondent is prohibited from performing more than 10 surgical procedures of any kind, during any seven-day period (week), other than surgical procedures that must be done during that week because of a bona-fide medical emergency. For the purpose of this paragraph, "surgical procedures" includes insertion of penile implants, removal of penile implants, vasectomies, circumcisions, evacuation of hematomas, evacuation of seromas, or any other urological or general surgical procedures conducted under local or general anesthesia. If Respondent exceeds 10 surgical procedures within a week because of a bona-fide medical emergency, the number of permitted surgical procedures during the immediately following week shall be reduced by the number of surgical procedures that exceeded ten during the previous week.

All new patients treated by the Respondent shall be notified in writing during their first visit after the effective date of this Decision, that in order to enable Respondent to be personally

available to address their needs, he has agreed with the Medical Board of California that, with exception of any bona-fide medical emergency, he shall not perform more than 10 surgical procedures of any kind, per week. All current patients shall be given the same written notification no later than 30 days after the effective date of this Decision.

Respondent shall maintain a log of all patients to whom the required notification was made. The log shall contain 1) the patient's name, address, phone number and email address; 2) the patient's medical record number, if available; 3) the full name of the person making the notification; 4) the date the notification was made; and 5) a description of the notification given. Respondent shall keep this log in a separate file or ledger, in chronological order, shall make the log available for immediate inspection and copying on the premises at all times during business hours by the Board or its designee, and shall retain the log for the entire term of probation.

Respondent shall maintain a log of all surgical procedures he performs. The log shall contain 1) the patient's name, address, phone number and email address; 2) the patient's medical record number, if available; 3) a description of the surgery; 4) the date and time the surgery was performed, and 5) those in attendance. Respondent shall keep this log in a separate file or ledger, in chronological order, shall make the log available for immediate inspection and copying on the premises at all times during business hours by the Board or its designee, and shall retain the log for the entire term of probation.

2. RECORDING AND RETENTION OF INFORMED CONSENT PROCESS COMMUNICATIONS. "Informed consent process" includes any and all communications between a patient and Respondent or any of Respondent's employees, during which Respondent or his employees provide information to patients in order to obtain patients' informed consent for any surgical procedure, and for which Respondent bears ultimate responsibility. To ensure that Respondent provides adequate informed consent to all of his surgical patients, during probation, Respondent shall audio or video record all of his or his employees' discussions with patients that are a part of the informed consent process. Respondent shall preserve all of email communications with patients that are a part of the informed consent process.

Respondent shall retain in each patient's medical record all audio or video recordings,

email communications, and any other communications between patients and Respondent or his employees that are a part of the informed consent process.

All patients being treated by Respondent shall be notified in writing that the Respondent has agreed with the Medical Board of California to audio or video record, and retain in the patient's medical record, all of the communications related to the informed consent process for any surgical procedure. All new patients must be provided this notification at the time of their initial consultation with Respondent, his employees or representatives. All current patients who have not yet had surgery by Respondent shall be provided the same notification no later than 30 days after the effective date of this Decision.

Respondent shall maintain a log of all patients to whom the required notification was made. The log shall contain 1) the patient's name, address, phone number, and email address; 2) the patient's medical record number, if available; 3) the full name of the person making the notification; 4) the date the notification was made; and 5) a description of the notification given. Respondent shall keep this log in a separate file or ledger, in chronological order, shall make the log available for immediate inspection and copying on the premises at all times during business hours by the Board or its designee, and shall retain the log for the entire term of probation.

3. MEDICAL RECORD KEEPING COURSE. Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a course in medical record keeping approved in advance by the Board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six (6) months after Respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one (1) year of enrollment. The medical record keeping course shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A medical record keeping course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have

been approved by the Board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

4. PROFESSIONALISM PROGRAM (ETHICS COURSE). Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California Code of Regulations (CCR) section 1358.1. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six (6) months after Respondent's initial enrollment, and the longitudinal component of the program not later than the time specified by the program, but no later than one (1) year after attending the classroom component. The professionalism program shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A professionalism program taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the Board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

5. CLINICIAN -PATIENT COMMUNICATION COURSE. Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in the Clinician – Patient Communication Workshop offered by the University of San Diego Physician Assessment and Clinical Education Program (PACE Program) at University of San Diego. Respondent shall participate in and successfully complete that course. Respondent shall provide any information

and documents that the PACE Program may deem pertinent.

The course shall be taken at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had it been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

6. MONITORING - PRACTICE. Within 30 calendar days of the effective date of this Decision, Respondent shall submit to the Board or its designee for prior approval as a practice monitor(s), the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with Respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the Board, including but not limited to any form of bartering, shall be in Respondent's field of practice, and must agree to serve as Respondent's monitor. Respondent shall pay all monitoring costs.

The Board or its designee shall provide the approved monitor with copies of the Decision(s) and Accusation(s), and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision(s), Accusation(s), and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision(s) and Accusation(s), fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement for approval by the Board or its designee.

Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, Respondent's practice shall be monitored by the approved monitor. Respondent shall

make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

If Respondent fails to obtain approval of a monitor within 60 calendar days of the effective date of this Decision, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Respondent shall cease the practice of medicine until a monitor is approved to provide monitoring responsibility.

The monitor(s) shall submit a quarterly written report to the Board or its designee which includes an evaluation of Respondent's performance, indicating whether Respondent's practices are within the standards of practice of medicine and whether Respondent is practicing medicine safely. It shall be the sole responsibility of Respondent to ensure that the monitor submits the quarterly written reports to the Board or its designee within 10 calendar days after the end of the preceding quarter.

If the monitor resigns or is no longer available, Respondent shall, within 5 calendar days of such resignation or unavailability, submit to the Board or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If Respondent fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Respondent shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

In lieu of a monitor, Respondent may participate in a professional enhancement program approved in advance by the Board or its designee that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at Respondent's expense during the term of probation.

7. NOTIFICATION. Within seven (7) days of the effective date of this Decision, the Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the

Chief Executive Officer at every hospital where privileges or membership are extended to Respondent, at any other facility where Respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

8. SUPERVISION OF PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE NURSES. During probation, Respondent is prohibited from supervising physician assistants and advanced practice nurses.

9. OBEY ALL LAWS. Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

10. INVESTIGATION/ENFORCEMENT COST RECOVERY. Respondent is hereby ordered to reimburse the Board its costs of investigation and enforcement, in the amount of $ 55,000 (fifty-five thousand dollars) payable to the Medical Board of California. The amount is compromised, and pursuant to parties' agreement Respondent is hereby ordered to make his payment in full within 30 calendar days of the effective date of the Order. A payment plan shall not be approved. The filing of bankruptcy by respondent shall not relieve respondent of the responsibility to repay investigation and enforcement costs. Failure to pay costs as ordered shall be considered a violation of probation.

11. QUARTERLY DECLARATIONS. Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

12. GENERAL PROBATION REQUIREMENTS.

Compliance with Probation Unit

Respondent shall comply with the Board's probation unit.

Address Changes

Respondent shall, at all times, keep the Board informed of Respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

Place of Practice

Respondent shall not engage in the practice of medicine in Respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Travel or Residence Outside California

Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

In the event Respondent should leave the State of California to reside or to practice Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

13. INTERVIEW WITH THE BOARD OR ITS DESIGNEE. Respondent shall be available in person upon request for interviews either at Respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

14. NON-PRACTICE WHILE ON PROBATION. Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is defined as any period of time Respondent is not practicing medicine as defined in Business and

Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. If Respondent resides in California and is considered to be in non-practice, Respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice and does not relieve Respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event Respondent's period of non-practice while on probation exceeds 18 calendar months, Respondent shall successfully complete the Federation of State Medical Boards's Special Purpose Examination, or, at the Board's discretion, a clinical competence assessment program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two (2) years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for a Respondent residing outside of California will relieve Respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; General Probation Requirements; Quarterly Declarations.

15. COMPLETION OF PROBATION. Respondent shall comply with all financial obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. This term does not include cost recovery, which is due within 30 calendar days of the effective date of the Order, or by a payment plan approved by the Medical Board and timely satisfied. Upon successful completion of probation, Respondent's certificate shall be fully restored.

16. VIOLATION OF PROBATION. Failure to fully comply with any term or condition

of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

17. LICENSE SURRENDER. Following the effective date of this Decision, if Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, Respondent may request to surrender his or her license. The Board reserves the right to evaluate Respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall within 15 calendar days deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

18. PROBATION MONITORING COSTS. Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

19. FUTURE ADMISSIONS CLAUSE. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing action agency in the State of California, all of the charges and allegations contained in Accusation No. 800-2018-048274 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict license.

20. PENALTY RELIEF. Respondent may file a petition for early termination or

modification of probation two years after the effective date of the Decision in this case, but the effective date of any decision on Respondent's penalty relief petition shall not be sooner than three years after the effective date of this Decision. If Respondent ever petitions for early termination or modification of probation, or if an accusation and/or petition to revoke probation is filed against him before the Board, all of the charges and allegations contained in the Sixth Amended Accusation No. 800-2018-048274 shall be deemed true, correct and fully admitted by respondent for purposes of any such proceeding or any other licensing proceeding involving Respondent in the State of California.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorneys, Peter R. Osinoff and/or Derek O'Reilly Jones. I understand the stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Medical Board of California.

DATED: 3-21-24

JAMES JAMSHID ELIST, M.D.
Respondent

I have read and fully discussed with Respondent James Jamshid Elist, M.D. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/21/2024

PETER R. OSINOFF
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Medical Board of California.

DATED: March 21, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ROBERT MCKIM BELL
Supervising Deputy Attorney General

Electronically Signed

VLADIMIR SHALKEVICH
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 800-2018-048274

ROB BONTA
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Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Sixth Amended Accusation Against: **JAMES JAMSHID ELIST, M.D.** **8500 Wilshire Boulevard, Suite 707** **Beverly Hills, California 90211** **Physician's and Surgeon's Certificate A 35400,** **Respondent.**	Case No. 800-2018-048274 OAH No. 2021120299 **SIXTH AMENDED ACCUSATION**

PARTIES

1. Reji Varghese (Complainant) brings this Sixth Amended Accusation solely in his official capacity as the Executive Director of the Medical Board of California (Board).

2. On June 23, 1980, the Board issued Physician's and Surgeon's Certificate Number A 35400 to James Jamshid Elist, M.D. (previous name, Jamshid Elist, M.D.) (Respondent). That license was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2024, unless renewed.

JURISDICTION

3. Section 2227 of the Business and Professions Code (Code) provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Board deems proper.

STATUTORY PROVISIONS

4. Section 2234 of the Code, states:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
>
> (1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.
>
> (2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.
>
> (d) Incompetence.
>
> ...

5. Section 2266 of the Code states:

> The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

COST RECOVERY

6. Section 125.3 of the Code states:

> (a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the

administrative law judge may direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licensee that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licensee to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licensee who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licensee who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(I) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

DEFINITIONS AND STANDARD OF CARE

7. Penile dysmorphia, also known as Penile Dysmorphic Disorder (PDD), is a

psychological disorder in which an individual is excessively concerned about and preoccupied by a perceived deficit in the size of his penis. An individual often has a debilitating and excessive fear of judgement by others. PDD is a subset of body dysmorphic disorder and a diagnosis must meet the following criteria, as set forth in the Diagnostic and Statistical Manual of Mental Disorders (DSM–5):

A. Preoccupation with perceived defect or flaw (in this case penis appearance and/or size) that are not observable or appear slight to others;

B. At some point during the course of the disorder, the individual has performed repetitive behaviors or mental acts in response to appearance concerns; and

C. The preoccupation causes clinically significant distress or impairment in social, occupational, or other areas of functioning.

8. The standard of care in the medical community provides that the treatment of PDD should be focused on psychotherapy, cognitive behavioral therapy and, in some instances, pharmacotherapy (such as anti-depressants). PDD is a chronic illness. Upon intake, a formal psychological evaluation should be obtained or performed, or a referral made to a mental health professional. It is not within the standard of care in the medical community to offer a surgical penile augmentation to a patient with a diagnosis of penile dysmorphia.

9. The standard of care in the medical community provides that the antibiotic prophylaxis recommended regimen for penile implant surgery is administration of an Aminoglycoside plus first or second-generation Cephalosporin or Vancomycin (an alternative protocol of Aminopenicillin β-lactamase inhibitor, including Ampicillin/Sulbactam Ticarcillin, or Tazobactam is acceptable). The standard of care further provides that prophylactic antibiotic administration should be initiated within one hour before the surgical incision or two hours before, for vancomycin or quinolones. Rifampin, an antibiotic typically used to treat tuberculosis, is not recommended as a postoperative antibiotic, as it has no systemic effectiveness in the post-surgical setting.

10. The standard of care in the medical community provides that the procedure of dividing the suspensory ligament of the penis, or tight suspensory ligament release, for increasing penile length in adults is not safe or efficacious.

11. Penile implant removal surgery can be difficult and result in injury and permanent damage to the neurovascular bundle (the nerve bundle that is responsible for penile sensation and located in the dorsa-lateral aspect, exactly where the Penuma implant is positioned during the implantation). Other consequences listed in the peer review literature are penile shortening, permanent numbness, and permanent erectile dysfunction. The challenges of these surgeries are well-documented in published literature.

12. The Penuma implant is a soft silicone, subcutaneous penile implant developed by Respondent.

13. The Penuma implant is not approved by the U.S. Food and Drug Administration (FDA). Instead, during the relevant time period, the Penuma implant had FDA clearance (510(K)) for use by Respondent, and only Respondent, in his practice. FDA clearance of the Penuma implant was based on representations from International Medical Devices, Inc. (IMD), the "manufacturer and 501(k) owner" - "official contact: James Elist, MD," that the Penuma implant is substantially similar to predicate devices on the market. The predicate devices that IMD and, therefore, Respondent compared the Penuma implant to were calf and gluteal implants made of the same dimension and design and similar material. The clearance is further based upon IMD's representation that the "unique anatomy, physiology, and function of the penis does not increase overall potential risks" compared to these predicate devices.

14. Contrary to IMD and, therefore, Respondent's representations to the FDA, the standard of care in the medical community recognizes the complex anatomy of the penis and that the delicate and easily disturbed mechanism of the penile erection makes the penis a structure that can be easily damaged or disturbed. Vital blood supply and essential nerves responsible for sensory and erectile function of the penis are positioned in the dorsolateral aspect on top of tunica albuginea. This is the exact location where the space for the Penuma implant is made. Insertion of the implant has a potential to compromise the blood supply and innervation of the penis.

Further, placement of permanent sutures on the undersurface of the glans can lead to disfigurement, transient or permanent numbness, chronic pain, altered sensation and multiple subsequent medical procedures.

15. Scarase is an oral supplement developed by Respondent that he has manufactured exclusively for use in his practice and sale to his patients. According to Respondent, Scarase is taken to decrease scar tissue. The main ingredients are protease, lipase, papain, bromelain and Serrapeptase. Scarase has not been the subject of any clinical studies or patent, but according to Respondent is similar to other products on the market and has shown positive results in his clinical observation. Respondent often provides his patients with a sample of Scarase following surgery. The patients can then buy more Scarase online or, when available, at the pharmacy located adjacent to his practice on Wilshire Boulevard in Beverly Hills, California. A bottle of Scarase costs approximately $55.00, a price set by Respondent. Respondent makes between $10.00 to $15.00 per bottle of Scarase sold.

16. The standard of care in the medical community provides that the operating physician and surgeon must arrange and coordinate for an expeditious evaluation of any postoperative patient, especially a patient with an implant and suspected infection. The standard of postoperative care is that the operating physician and surgeon evaluate and examine a patient after surgery until full recovery, or at a minimum, arrange for such follow-up with another implant surgeon with whom the operating surgeon has communicated about the patient.

17. The standard of care in the medical community further provides that it is the operating physician and surgeon's responsibility to arrange for a patient's postoperative suture, staples, or drain removal either in the physician and surgeon's office or to coordinate with a colleague, if a patient comes from a long distance. In rare instances, as an alternative, a physician and surgeon can provide training to a patient or caretaker on suture removal and provide the supplies to do so at home.

18. The standard of care in the medical community provides that it is unethical to engage in the practice of having patients sign a "release of claims" in exchange for performing penile implant removal surgery at no cost.

19. The standard of care in the medical community provides that it is unethical for a physician to offer to compensate a patient in exchange for removing comments on social media regarding the care and treatment the patient received from the physician.

FACTUAL ALLEGATIONS

20. During the relevant time period, Respondent operated a solo urology practice in Beverly Hills, California. As part of that practice, Respondent performed outpatient surgeries at the Beverly Hills South Pacific Surgery Center, also located in Beverly Hills, California.

21. During the relevant time period, Respondent's practice primarily consisted of performing Penuma penile implant surgeries.

22. During the relevant time period, Respondent maintained a public webpage, www.drelist.com – through which he advertised and described his practice, in particular, penile enhancement surgery using the Penuma implant.

23. Respondent has medical assistants and an office manager/consultant who assist him in his practice. These individuals are not licensed physicians and surgeons, physician assistants, or registered nurses. According to Respondent, these individuals communicate with the patients and respond to patient inquiries, in addition to arranging patients' payments, under his supervision.

24. Between 2014 and 2018, Respondent employed an individual, Omead M., in his practice. Omead M. was finishing medical school and applying for residencies during this time, but held no license in California, as a physician and surgeon, physician assistant, or any other type of health care provider. Respondent asserts that he did not refer to Omead M. as "doctor" and that he instructed Omead M. not to call himself "doctor."

25. According to Respondent, while under his supervision, Omead M. performed medical assistant activities not requiring a license, such as answering emails and writing history and physical findings. Throughout Omead M.'s email correspondences with Respondent's patients, Omead M. states that he is under the supervision of Respondent, and refers to himself and is referred to as "Dr. Omead."

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The Complaint

26. On or about September 25, 2018, the Board received a complaint against Respondent from a patient who had undergone penile enhancement surgery with Respondent in 2013 ("Patient 0").[1]

27. More specifically, Patient 0 reported that, in or about July 2013, he contacted Respondent's office for information regarding penile enhancement procedures after reading about Respondent's practice on the internet. When Patient 0 was told the price of the procedure, he was dissuaded and did not pursue the procedure further with Respondent's office or elsewhere.

28. Approximately two months later, Respondent's office called Patient 0 and invited him to enter a contest Respondent was running in which the winner would receive free penile enhancement surgery in exchange for appearing in a documentary on his progress. Respondent's office informed Patient 0 that the documentary was financed by rapper Percy Miller, also known as "Master P."

29. Respondent's office then emailed Patient 0 a flyer about the contest. The flyer advertised a free penile enlargement procedure to a volunteer who would share his penis enhancement experience with "[a]n accredited team of documentary reporters and directors... currently conducting an interview with [Respondent] to include in a documentary film about 'history of male sexuality and genital enhancement.'" The flyer directed those interested to contact Respondent's office.

30. Patient 0 entered the contest and, about three weeks later, received notice that he had won.

31. In late September 2018, Patient 0 traveled from his home in Massachusetts to Beverly Hills, California, for the procedure. According to Patient 0, Respondent's office had promised to reimburse him the entire cost of his airfare, hotel and transportation to the surgery center and half the cost of his food. Patient 0, however, only received $300 from Respondent for his costs associated with the trip.

[1] In order to protect this patient's privacy, he is referred to as "Patient 0." His true name is known to Respondent and was disclosed during discovery.

32. Upon arriving at his hotel in Beverly Hills, Patient 0 participated in a preoperative interview with Respondent and Master P about why he had selected Respondent's penile implant. According to Patient 0, he was given scripted answers. At that meeting, Respondent, Patient 0 and Master P signed a contract stating that 1) Patient 0 would receive a penile implant and have his progress filmed; 2) Master P would pay for the implant procedure and documentary crew; and 3) Respondent would perform the procedure. Patient 0 asked for a copy of the contract, but did not receive one.

33. On or about October 1, 2013, Patient 0 arrived at Respondent's office for his preoperative examination. Respondent documented penile dysmorphia and tight suspensory ligament as the chief complaint and diagnosis. Respondent did not document any evaluation of Patient 0's PDD, including obtaining or performing a formal psychological evaluation, or making a referral to a mental health professional. Respondent also did not document any evaluation of the suspensory ligament. Respondent's surgical plan for Patient 0 included suspensory ligament release. Respondent performed the procedure that same day. The operative report states that the "suspensory ligament was identified and preserved."

34. Patient 0 saw Respondent again the next day when they participated in an interview together for the documentary. Patient 0 was interviewed repeatedly in the following days and was instructed on how to answer, including that he would recommend the surgery to family or friends.

35. After Patient 0 returned to Massachusetts, he continually updated Respondent on his condition with statements and photographs.

36. Patient 0 reported that between November 2013 and January 2018, he experienced periodic painful swelling in the surgical area.

37. In or around January 2018, Patient 0 believes the implant detached from the base of the penile head and began to move freely around the circumference of his penis shaft. This caused him significant pain. Patient 0 emailed Respondent about the problem and included photographs.

38. Respondent informed Patient 0 that the implant would need to be removed. Respondent informed Patient 0 that he would remove the implant for free, but that Patient 0 would have to pay $3,500.00 to cover the costs of the surgery center and anesthesia. Patient 0 did not think this was right and demanded his medical records and a copy of the contract he signed with Master P and Respondent.

39. In June 2018, Respondent sent Patient 0 his operative report, but none of the other requested documents.

40. Though he continued to be in pain, Patient 0 did not want Respondent operating on him again. He sought treatment from other providers instead.

41. In response to his complaint, the Board opened an investigation into Respondent's practice.

Patient 1[2]

42. After learning about Respondent's practice on YouTube, on or about February 25, 2018, Patient 1 first contacted Respondent's office, via email, to inquire about penile enlargement.

43. After undergoing a circumcision procedure with another provider, in April 2018, Patient 1 elected to undergo penile enhancement surgery, as well as suprapubic fat removal, with Respondent.

44. On or about July 20, 2018, Patient 1 presented to Respondent for an initial consultation and preoperative examination. Respondent documented penile dysmorphia and tight suspensory ligament as the chief complaint and diagnosis. Respondent did not document any formal testing or evaluation to support the DSM-V diagnosis of PDD. The physical examination stated, "testes are not normal size and consistent with testicular atrophy" and phallus is stated to be "within normal limits." Respondent's treatment plan provided for surgery: removal of suprapubic fat, insertion of subcutaneous penile implant (Penuma implant) and release of tight

[2] In order to protect patient privacy, the patients at-issue in this charging pleading are identified by number (e.g., Patient 1). The true names of the referenced patients are known to Respondent and were disclosed during discovery.

suspensory ligament. Respondent performed surgery on Patient 1 that same day.

45. On or about July 20, 2018, Patient 1 signed a "Release of Claims" in exchange for Respondent's limited lifetime warranty on the Penuma implant.

46. Following the surgery, on or about September 11, 2018, Patient 1 emailed Respondent complaining of swelling.

47. On or about October 5, 2018, Respondent diagnosed Patient 1 with a skin infection in the operative area. Respondent documented recommending that he follow up in three weeks. Respondent also recommended Nitro Bid cream to help blood flow to the skin.

48. In the following weeks, Patient 1 continued to complain of pain and emailed Respondent that he was afraid the implant would perforate the skin.

49. Patient 1 returned to Respondent on or about November 1, 2018. Respondent documented Patient 1's chief complaints as protruding top shaft and severe scar tissue. Specifically, the implant was protruding through the skin. That same day, Respondent performed penile enhancement revision surgery and removed the Penuma implant, along with scar tissue.

50. On or about November 1, 2018, Patient 1 executed a "Release of Claims." It is unclear what Patient 1 received in exchange for signing the "Release of Claims."

51. After the implant was removed, the incision at the top of Patient 1's pubic region did not heal. The site oozed blood and was painful.

52. On or about December 3, 2018, Patient 1 emailed a photograph to Respondent that was clinically suspicious for postoperative infection.

53. Patient 1 received an email response from Respondent's office recommending he apply Neosporin, an over-the-counter antibiotic ointment, and make an appointment as soon as possible.

54. On or about December 7, 2018, Patient 1 went to UC Irvine Health and was treated for a suprapubic abscess.

55. On or about December 10, 2018, Patient 1 and Respondent executed a Settlement Agreement and Release of Claim pursuant to which Patient 1 released Respondent from liability for any injuries related to the July 20, 2018, and November 1, 2018, procedures. Additionally,

the agreement provided that Patient 1 would remove any and all social media posts Patient 1 made regarding the care and treatment he received from Respondent and that he would refrain from making any further public disclosures about the care and treatment he received from Respondent. In exchange, Respondent would pay Patient 1 $5,000. Respondent conditioned receipt of the payment on Patient 1 first removing all negative social media posts, including from the website, Phalloboards.

56. Phalloboards is an online forum for discussing penile enhancement techniques.

57. Respondent committed an extreme departure from the standard of care when he failed to take action to have Patient 1 urgently evaluated when, on December 3, 2018, Patient 1 emailed Respondent photographs clinically suspicious for postoperative infection. Instead, Respondent suggested he apply Neosporin.

58. Respondent's care and treatment of Patient 1 further departed from the standard of care as follows:

A. Respondent diagnosed Patient 1 with PDD without a proper evaluation - specifically, without obtaining or performing a formal psychological evaluation of Patient 1, or making a referral to a mental health professional. Respondent then recommended implant surgery even though the physical examination did not support the chief complaint or assessment.

B. Respondent documented planning a release of the suspensory ligament for Patient 1, even though this procedure is not considered safe.

C. After documenting in Patient 1's note, "tight suspensory ligament," Respondent then failed to document any description of the suspensory ligament in Patient 1's operative notes. Instead, in the operative case dictation, it is stated: "suspensory ligament was identified and preserved." Respondent's documentation is inconsistent and inaccurate and appears template when compared to that of his other patients.

D. Respondent had Patient 1 sign a "Release of Claims" in exchange for performing future removal surgery at no cost.

E. Respondent offered Patient 1 a monetary payment in exchange for removing Patient 1's social media posts regarding the care and treatment he received from Respondent.

Patient 2

59. On or about August 27, 2018, Patient 2 presented for surgery with Respondent. A preoperative examination was conducted. Respondent documented penile dysmorphia and tight suspensory ligament as chief complaint and diagnosis. Patient 1 completed a questionnaire that indicated he was dissatisfied with his penis, but Respondent did not document any formal testing or evaluation to support the DSM-V diagnosis of PDD. The physical examination stated, "testes are not normal size and consistent with testicular atrophy" and phallus is stated to be "within normal limits." Respondent's treatment plan provided for surgery: subcutaneous penile implant with silicone block (Penuma implant) and suspensory ligament release.

60. On or about August 27, 2018, Patient 2 signed a "Release of Claims" in exchange for Respondent's limited lifetime warranty on the Penuma implant.

61. On or about October 22, 2018, Patient 2 informed Respondent, via email, that he was experiencing bumps at the incision site. Respondent's office replied that the bumps were the internal sutures and that they would dissolve on their own.

62. On or about January 2, 2019, Patient 2 emailed Respondent. Patient 2 reported that on December 30, 2018, he had a high fever and that he was experiencing severe pain and inflammation. Patient 2 attached several photographs of his penis to the email. The photographs demonstrated a significant change in clinical presentation, specifically, new onset of swelling, erythema, loss of rugae, indicative of infection and inflammation.

63. Respondent's office emailed Patient 2 stating that Respondent had prescribed him two medications for pick up at Patient 2's pharmacy and requested that he follow up every other day or if there was any change.

64. On or about January 4, 2019, Patient 2 emailed Respondent complaining of painful erections and continued, but reduced, inflammation. Patient 2 attached additional photographs of his penis. Respondent recommended that he use aloe vera or oil and resume use of Turbigrip, a tubular bandage.

65. On or about January 29, 2019, Patient 2 sent Respondent photographs indicating the implant's impending erosion. Patient 2 complained of intolerable pain and feeling like the

implant was protruding at the incision site.

66. On or about January 31, 2019, Patient 2 presented to Respondent for further surgery. Respondent removed the implant that day.

67. Patient 2 executed a "Release of Claims," on or about January 31, 2019, which provided in part that Respondent would not charge him for the January 31, 2019, removal procedure.

68. Respondent committed an extreme departure from the standard of care in his postoperative treatment of Patient 2. Specifically, after Respondent received photographs from Patient 2, on or about January 2, 2019, indicating infection, Respondent failed to offer Patient 2 a timely evaluation. Respondent should have expeditiously examined Patient 2 upon receiving photographs showing new onset of severe swelling four (4) months after surgery, and after a period of normal examination, as this is an indication of infection or another acute process. Instead, Respondent recommended that the patient use aloe vera or oil and resume the use of Turbigrip.

69. Respondent's care and treatment of Patient 2 further departed from the standard of care as follows:

A. Respondent diagnosed Patient 2 with PDD without a proper evaluation - specifically, there is no documentation that Respondent obtained or performed a formal psychological evaluation of Patient 2, or made a referral to a mental health professional. Respondent then recommended implant surgery.

B. Respondent diagnosed Patient 2 with a tight suspensory ligament even though the preoperative examination and photographs do not support this diagnosis. The preoperative photographs indicate normal testicles without atrophy. Though there was no finding of a tight ligament, Respondent documented, that "testes are not normal size and consistent with testicular atrophy." This note is inaccurate as it contradicts the findings of the physical examination. Respondent admits this note is a template.

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C. Respondent prescribed Patient 2 Rifampin post-operatively. Respondent has stated that he prescribed Rifampin post-operatively until 2018 or 2019 believing that to be the standard of practice at the time.

D. Respondent had Patient 2 sign a "Release of Claims" in exchange for performing removal surgery at no cost.

Patient 3

70. Patient 3 presented to Respondent's office for a preoperative consultation and examination on or about August 13, 2018. Respondent documented penile dysmorphia as the diagnosis. Respondent did not document any formal testing or evaluation to support the DSM-V diagnosis of PDD. Respondent's record for the physical examination states, "testes are palpable in the scrotum and are not normal size consistent with testicular atrophy." Patient 3's testes, however, appeared normal size in the preoperative photographs. Respondent documented the planned procedures as subcutaneous penile implant with silicone block (Penuma implant) and release of tight sensory ligament.

71. On or about August 13, 2018, Patient 3 signed a "Release of Claims" in exchange for Respondent's limited lifetime warranty on the Penuma implant.

72. On or about August 14, 2018, Patient 3 presented to Respondent for penile implant surgery and a vasectomy.

73. In the weeks following his surgery, Patient 3 consistently emailed Respondent's office with progress updates and photographs. Patient 3 expressed concern about curvature, and fluid build-up around the implant. Patient 3 was told he was healing normally and was advised on the use of a Turbigrip and Scarase to help in the recovery process.

74. Patient 3 continued to email Respondent photographs of his progress and complained that the implant was palpable and protruding.

75. On or about October 30, 2018, Patient 3 emailed Respondent's office requesting the consent form he signed and his medical records from Respondent. He reported a complication with his incision line and requested information about Respondent's refund policy. Patient 3's incision line was continuing to bleed over two months after surgery.

76. On or about October 31, 2018, Respondent's office emailed Patient 3 that they would need some time to gather the requested paperwork. Patient 3 was also informed that there was no refund policy, but instead a warranty on the implant - if there is a complication, Respondent will perform any necessary corrective or removal surgery at no cost. Patient 3 will only have to pay for the cost of the anesthesiologist.

77. In an email dated October 31, 2018, Patient 3 again expressed his concerns about the incision line and also that the implant was protruding. Patient 3 attached photographs.

78. In an email dated November 1, 2018, Respondent's office instructed Patient 3 to consult with a dermatologist, in response to his concerns about the incision line. The protrusions he was experiencing were attributed to the implant bending, which was normal and would subside in time.

79. In an email dated November 2, 2018, Respondent's office informed Patient 3 that Respondent had examined his photographs and attributed the protrusions to scar tissue. He was again advised to see a dermatologist.

80. Patient 3 decided to have the implant removed and requested a refund from Respondent. Respondent's office would not grant a refund, but offered to perform the removal for $3,000 which covered the anesthesiologist's fee.

81. On or about November 26, 2018, Respondent removed Patient 3's Penuma implant.

82. On that same day, Patient 3 executed a "Release of Claims." It is unclear what Patient 3 received in exchange for signing the "Release of Claims."

83. Patient 3 was discharged with a permanent suture in place. At the time of discharge, Respondent did not document a plan for the removal of the suture or provide Patient 3 with any instructions or supplies for self-removal of the suture.

84. In an email dated December 20, 2018, Respondent's office instructed Patient 3 to remove the suture himself.

85. On or about January 13, 2019, as part of his follow up care, Patient 3 emailed Respondent photographs of his progress. Patient 3 complained that his penis hung too high in its flaccid state, about excessive curvature when erect and scar tissue.

86. Patient 3 continued to complain about the high angle at which his penis hung post-surgery and, on or about February 4, 2019, Respondent instructed Patient 3 to start using Kenalog, a synthetic corticosteroid, and called a prescription in to Patient 3's pharmacy.

87. On or about February 24, 2019, Patient 3 signed a Settlement Agreement and Release of All Claims pursuant to which he would be paid $5,000 in exchange for releasing Respondent from liability for the August 14, 2018, and November 26, 2018, penile implant procedures. Patient 3 also agreed not to make any disparaging public remarks about Respondent or his surgeries on social media, including on the website Phalloboards. Patient 3 further agreed to remove any disparaging remarks he had already posted about Respondent and/or the surgeries in public forums, including from the website Phalloboards.

88. On that same day, Respondent gave Patient 3 a check for $5,000.

89. Respondent also gave Patient 3 a photocopy of another check that Respondent made out to Patient 3 for $1,000.00. According to Respondent, he retained the actual check to give to Patient 3 after he removed his comments on social media, including from the website, Phalloboards, so other patients would not be adversely affected by Patient 3's purportedly inaccurate statements.

90. Respondent never gave Patient 3 the $1,000.00 check because Patient 3 never removed all of his social media comments about Respondent and his practice.

91. Respondent committed the following departures from the standard of care in his care and treatment of Patient 3:

A. Respondent maintained inaccurate records for Patient 3. Specifically, Patient 3's preoperative photographs indicate normal size testicles. Respondent documented, however, that testes are "not normal size consistent with testicular atrophy." This note is inaccurate as it contradicts the findings of the physical examination. The note appears to be a template, as it mirrors that made of the physical examination of several of Respondent's other patients.

B. Respondent diagnosed Patient 3 with PDD without a proper evaluation - specifically, there is no documentation that Respondent obtained or performed a formal psychological evaluation of Patient 3, or made a referral to a mental health professional. Respondent then

recommended implant surgery.

C. Respondent documented planning a release of the suspensory ligament for Patient 3, even though this procedure is not considered safe.

D. Respondent failed to properly evaluate and/or examine Patient 3 post-operatively. In response to Patient 3's concerns about the implant, Respondent referred him to a dermatologist. Photographs submitted by Patient 3, however, suggested an underlying process that Respondent should have evaluated and examined, or at least, arranged for such follow up with another implant surgeon with whom Respondent had communicated about Patient 3.

E. On November 26, 2018, Respondent left an external permanent suture in place and discharged Patient 3 without a clearly outlined postoperative care plan for the suture removal. Not only did Respondent fail to arrange for Patient 3's suture removal post-operatively either at his office, or that of another medical provider, but Respondent also failed to provide any training to Patient 3 or his caretakers on suture removal, or the necessary supplies. Instead, Respondent provided instructions to Patient 3 in an email, weeks after the implant removal surgery.

F. Respondent had Patient 3 sign a "Release of Claims" in exchange for performing future removal surgery at no cost.

G. Respondent also offered to, and did, compensate Patient 3 for agreeing to remove social media comments, including on Phalloboards, that Patient 3 had posted regarding the care and treatment he received from Respondent.

Patient 4

92. In March 2018, Patient 4 contacted Respondent's office regarding penile enlargement surgery.

93. On or about May 10, 2018, Patient 4 presented for a preoperative examination and evaluation. Patient 4's preoperative photographs show a normal size phallus and genitalia without evidence of testicular atrophy or a tight sensory ligament. Respondent's preoperative note for Patient 4 states the chief complaint as "desires penile enhancement, penile dysmorphia and tight suspensory ligament." With respect to the physical examination, Respondent documented that, "testes are palpable in the scrotum and are not normal size consistent with testicular atrophy."

The phallus was documented to be "within normal limits." Respondent did not document any evaluation of Patent 4's PDD, including obtaining or performing a formal psychological evaluation, or making a referral to a mental health professional. Respondent also did not document any evaluation of the suspensory ligament. Respondent's surgical plan for Patient 4 included subcutaneous penile implant with silicone block (Penuma implant) and release of tight sensory ligament.

94. On or about May 10, 2018, Patient 4 signed a "Release of Claims" in exchange for Respondent's limited lifetime warranty on the Penuma implant.

95. On or about May 11, 2018, Patient 4 underwent penile implant surgery with pubic fat removal. The operative note states that the "suspensory ligament was identified and preserved," which contradicts Respondent's surgical plan for Patient 4. The operative note also lists Vancomycin and Gentamicin as the perioperative antibiotics. The anesthesia record, however, lists Ancef and Gentamicin.

96. Two weeks following the surgery, Patient 4 emailed Respondent concerned that the implant was "off center." He also complained of pain, swelling, and curvature. Patient 4 attached photographs to his email.

97. On or about June 8, 2018, Patient 4 sent Respondent's office an email, with photographs, expressing concern that he was losing penile length and experiencing swelling.

98. A week later, he emailed Respondent concerned that the implant was misaligned. Patient 4 again attached photographs.

99. On or about June 21, 2018, Patient 4 presented for an in-person visit with Respondent to address his concerns and post-surgical progress. At the appointment with Respondent, Patient 4 discussed scheduling revision surgery to correct the alignment of the Penuma implant.

100. Patient 4 continued to email Respondent Patient 4's photographs and complaints of swelling, pain and misalignment of the implant.

101. On or about August 28, 2018, Patient 4 underwent further surgery with Respondent – specifically, scar tissue removal and removal and replacement of the implant.

102. On or about August 28, 2018, Patient 4 executed a "Release of Claims."

103. Respondent's care and treatment of Patient 4 departed from the standard of care as follows:

A. Respondent planned a release of the suspensory ligament for Patient 4, after documenting in Patient 4's note, "tight suspensory ligament." A release of the suspensory ligament, however, is not considered a safe procedure.

B. Respondent maintained conflicting and inaccurate records for Patient 4. For example, preoperative pictures revealed a normal size phallus and genitalia, yet Respondent documented Patient 4 as having testicular atrophy and a tight suspensory ligament. As such, the photographs do not support the diagnosis. Respondent then documented that his treatment plan included a release of the suspensory ligament, while his operative note states that the sensory ligament was preserved. Additionally, the operative note and anesthesia records list different perioperative antibiotics.

C. Respondent diagnosed Patient 4 with PDD without a proper evaluation - specifically, there is no documentation that Respondent obtained or performed a formal psychological evaluation of Patient 4, or made a referral to a mental health professional. Respondent then recommended implant surgery.

D. Respondent had Patient 4 sign a "Release of Claims" in exchange for Respondent's "warranty" on the penile implant and procedure.

Patient 5

104. Patient 5 first contacted Respondent's office regarding penile enhancement surgery on or about January 13, 2015.

105. On or about July 13, 2015, Patient 5 presented to Respondent for penile implant surgery and a vasectomy. Respondent documented Patient 5's chief complaint as: desires penile enhancement, penile dysmorphia and tight suspensory ligament. Patient 5, however, did not show low self-esteem or confidence with respect to his penis and/or sex life on Respondent's preoperative questionnaire. Despite this inconsistency between Respondent's diagnosis of PDD, Patient 5's desire for enhancement surgery and Patient 5's positive responses to questions regarding his perception of his penis, Respondent did not refer him for psychotherapy. With

respect to the physical examination, Respondent documented that, "testes are palpable in the scrotum and are not normal size consistent with testicular atrophy." The phallus was documented to be "within normal limits." Respondent's plan for Patient 5 included subcutaneous penile implant with silicone block (Penuma implant) and release of tight sensory ligament.

106. The antibiotic administration record for Patient 5's July 13, 2015, surgery indicates that Gentamicin and Ancef were administered. Respondent's July 13, 2015, operative report, however, states that Vancomycin was administered pre-operatively.

107. Following the surgery, Patient 5 repeatedly complained of a painful protruding sensation. All of Patient 5's post-surgical email communications with Respondent's office were with "Dr. Omead."

108. On or about August 21, 2015, Patient 5 emailed "Dr. Omead" complaining about a bump on the right side of his penis. "Dr. Omead" told Patient 5 that Respondent would need to redo a suture.

109. On or about September 10, 2015, Respondent surgically revised the original implant sutures, leaving the implant in place. Patient 5 had been suffering from discomfort and bulging at the tip of his penis.

110. On or about September 10, 2015, Patient 5 executed a "Release of Claims."

111. Following the second surgery, and for the next few months, Patient 5 continued to email Respondent's office complaining about the "bump," or "bulge," on the right side. Patient 5 included photographs. Patient 5 was told that it was likely a wrinkle in the implant and, on or about November 6, 2015, was advised to wear a Turbigrip compression sock to help reduce the swelling.

112. On or about March 19, 2016, Patient 5 sent Respondent's office an email expressing his concern that the right side of his implant "was bulging out." The implant seemed to be misaligned. Patient 5 sent an illustration describing the implant position.

113. Respondent informed Patient 5 that he needed a larger implant.

114. On September 9, 2016, Patient 5 underwent penile revision surgery again with Respondent, who replaced Patient 5's implant with a larger implant.

115. On or about September 9, 2016, Patient 5 executed a "Release of Claims" in exchange for Respondent performing implant removal surgery at no cost.

116. Respondent committed the following departures from the standard of care in his care and treatment of Patient 5:

A. Respondent failed to maintain accurate records for Patient 5. For example, there is a discrepancy between the operating room antibiotic administration record and the note in the operative record of the antibiotic administered. The operating room antibiotic administration record states Gentamicin and Ancef were administered, while the operative report states that Vancomycin was administered pre-operatively.

B. Respondent diagnosed Patient 5 with PDD without a proper evaluation - specifically, there is no documentation that Respondent obtained or performed a formal psychological evaluation of Patient 5, or made a referral to a mental health professional. Respondent then recommended implant surgery.

C. Respondent prescribed Patient 5 a home regimen of oral Rifampin as part of his postoperative care. Respondent has stated that he prescribed Rifampin post-operatively until 2018 or 2019 believing that to be the standard of practice at the time.

D. Respondent had Patient 5 sign a "Release of Claims" in exchange for performing implant removal surgery at no cost.

Patient 6

117. On or about May 24, 2016, Patient 6 contacted Respondent's office asking who he could call with questions. Patient 6 was instructed to contact "Ray" or "Dr. Omead."

118. On or about July 19, 2016, Patient 6 presented to Respondent for penile implant surgery. A preoperative examination was performed that same day. Respondent documented penile dysmorphia and subcutaneous penile implant desired as the chief complaint. Respondent did not document any formal testing or evaluation to support the DSM-V diagnosis of PDD. Respondent did not refer Patient 6 for psychological testing. The physical examination stated, "testes are not normal size and consistent with testicular atrophy" and phallus is stated to be "within normal limits." Respondent's treatment plan provided for surgery: insertion of

subcutaneous penile implant (Penuma implant) and release of tight suspensory ligament. Respondent performed surgery on Patient 6 that same day.

119. On or about July 19, 2016, Patient 6 signed a "Release of Claims" in exchange for Respondent's limited lifetime warranty on the Penuma implant.

120. On or about July 31, 2016, Patient 6 emailed Respondent's office inquiring about the removal of his stitches. Photographs show a blue non-absorbable Prolene suture at the surgery site. A response email from Respondent's office states, "[t]he two blue drain hold sutures need to be removed this week. If you are not familiar with how to remove them, please consult with your local physician or urgent care center to remove them."

121. On August 1, 2016, Patient 6 emailed Respondent's office that his wife had removed the stitches.

122. Between July 2016, and March 2017, Respondent's office informed Patient 6 that he was healing well and that his length would increase after the sutures dissolved. Patient 6 was advised to continue using a Turbigrip and Nitro-Bid to restore sensation to the shaft. Patient 6 continued to complain of numbness, decreased length, lack of sensation causing inability to achieve orgasm, and varying degrees of irritation. "Dr. Omead" provided the responses to Patient 6's progress photographs and inquiry emails, under Respondent's supervision.

123. Ultimately, Patient 6 scheduled an appointment with Respondent to have the Penuma implant removed. In a March 9, 2017, email, "Dr. Omead" of Respondent's office told Patient 6 that after removal, Patient 6's penis should return to its original size and feeling.

124. On or about March 21, 2017, Respondent removed Patient 6's subcutaneous Penuma implant.

125. On that same day, Patient 6 executed a "Release of Claims." It is unclear what Patient 6 received in exchange for signing the "Release of Claims."

126. Following removal of the implant, Patient 6 continued to complain of loss of sensation to most of the penis shaft. He was also unable to achieve orgasm and had lost almost two (2) inches of length.

127. Respondent sent Patient 6, Kenalog to self-inject into his penis to help break up the scar tissue shortening his penis length, but the injections were ineffective.

128. On or about January 14, 2019, Respondent surgically removed scar tissue caused by Patient 6's implant.

129. On that same day, Patient 6 executed a "Release of Claims." It is unclear what Patient 6 received in exchange for signing the "Release of Claims."

130. Respondent committed the following departures from the standard of care in his care and treatment of Patient 6:

A. Respondent's care and treatment of Patient 6 departed from the standard of care when after Patient 6's implant surgery, he left an external permanent suture and discharged Patient 6 without a clearly outlined postoperative care plan for the suture removal. Respondent failed to arrange for Patient 6's suture removal post-operatively either at his office, or that of another medical provider. Respondent also failed to provide any training to Patient 6 or his caretakers on suture removal, or the necessary supplies.

B. Respondent diagnosed Patient 6 with PDD without a proper evaluation - specifically, there is no documentation that Respondent obtained or performed a formal psychological evaluation of Patient 6, or made a referral to a mental health professional. Respondent admits he did not refer Patient 6 for psychological testing. Instead, Respondent recommended implant surgery.

C. Respondent had Patient 6 sign a "Release of Claims" in exchange for Respondent's "warranty" on the penile implant and procedure.

D. Omead M., acting under Respondent's supervision, told Patient 6 that after removal, Patient 6's penis should return to its original size and feeling. This statement shows a lack of knowledge. It is well-established that implant removal will lead to penile length loss. Loss of sensation is a rare complication of penile implant surgery and the loss is not reversible by implant removal.

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Patient 7

131. On or about September 17, 2020, the Board received a complaint from Patient 7, who underwent a Penuma implant procedure by Respondent on July 23, 2020.

132. Patient 7 reached out to Respondent's office regarding Penuma implant in approximately June and July, 2020. Due to COVID-19 precautions Patient 7 did not have an in-person consultation until the day of the surgery, on July 23, 2020. Patient 7 brought a money-order and paid for the surgery.

133. At Respondent's office, on the day of surgery, Patient 7 was presented with various forms, including informed consent forms. Respondent was not present when the forms were signed. Patient 7 was asked to sign the forms by a member of Respondent's staff. Other than being asked to place his signature on the forms on an electronic device, Patient 7 was not given any information about the surgery. Patient 7 placed his initials next to a statement: "I have been offered independent pre-surgical psychological evaluation for this procedure, and respectfully decline undergoing such evaluation." Likewise, Patient 7 was asked to sign an "Informed Consultation Consent" in which it was indicated that "the Patient has been offered independent pre-surgical psychological evaluation for the contemplated procedure." However, there is no documentation other than these boiler-plate forms that any psychological evaluation has been offered or declined by patient. Respondent never offered and never referred Patient 7 for any psychological evaluation prior to Patient 7 undergoing penis enhancement surgery.

134. In the documents which Patient 7 was required to sign, Respondent included language to deter Patient 7 from seeking second opinions or medical care from other medical providers with regard to his implant: "I hereby certify that I will consult exclusively with Dr. Elist's office on any follow up consultations, questions, communications, procedures, and /or comments. Should I consult with or conduct any related procedures with any other professionals, Dr. Elist's office will not be held responsible or liable for any adverse events (physical or psychological) that may result."

135. After signing the forms, Patient 7 was taken to see Respondent. In a very abbreviated history and physical on the date of the surgery, Respondent noted that Patient 7

"lacks self-confidence" and "lacks self-esteem." In Patient 7's complaint to the Medical Board, Patient 7 stated that Respondent told him he had "body dysmorphia." Respondent himself did not perform and/or document any mental evaluation of Patient 7 to arrive at a diagnosis of body dysmorphic disorder, and did not document that diagnosis in Patient 7's record.

136. Penuma implant is not FDA approved. Rather, it has a 501 (k) clearance, dated from 2004, where the regulation specialty was Ear, Nose, and Throat. Respondent did not disclose to Patient 7 any information about the true state of Penuma's FDA registration, or the complications associated with this device. Patient 7 was then taken to surgery, which proceeded without any complications, according to Respondent's surgical note. Respondent did not record what size implant was used. Following the surgery, Patient 7 contacted Respondent's office with progressive swelling starting on August 5, 2020.

137. Patient 7 returned to see Respondent on August 6, 2020. According to Respondent's office note, Respondent informed Patient 7 that fluid accumulation is normal and the fluid would be absorbed. Patient 7 went to the UCLA emergency room and was told to return to see Respondent. On August 10, 2020, Patient 7 returned to see Respondent, who was unable to aspirate the fluid. Patient 7 was taken to surgery, at which time he underwent a hematoma evacuation by Respondent.

138. Patient 7 continued to have problems with pain and swelling. He presented to the emergency department at Martin Luther King Hospital on August 21, 2020 for drainage from surgical site, lower abdominal pain and palpitations. A CT scan of the pelvis showed an ill-defined pocket of fluid with several foci of gas in the anterior, lower pelvic abdominal wall. Physical exam was unremarkable, thought to be hematoma. Patient 7 was noted to have bizarre behavior and left against medical advice.

139. Patient 7 then presented to the emergency room at Cedars-Sinai on August 24, 2020, complaining of palpitations, tachycardia, fever and drainage from the lower abdominal incision site. He was worried that he was having a pulmonary embolism. This was ruled out by a chest CT and/or angiogram.

140. Respondent's medical records indicate that Patient 7 was seen on October 1, 2020, at which time no problems were noted. He was cleared to resume sexual activity.

141. Over the course of the month, Patient 7 had email communications with Dr. Elist's staff. He then eventually moved out of California. Due to continued discomfort, Patient 7 saw Dr. Hauser in Florida, due to suspicion for low-grade infection. The implant was removed on November 25, 2020. Pathology of surrounding tissue also showed dense fibroadipose tissue with foreign body giant cell reaction.

142. Respondent committed an extreme departure from the standard of care in his care treatment of Patient 7 by failing to disclose that the implant to be used has not been fully FDA-Approved.

143. Respondent committed an extreme departure from the standard of care when Respondent actively deterred Patient 7 from seeking medical care from other providers by having Patient 7 sign a certification that he will consult exclusively with Respondent's office on any follow-up consultations, questions, communications, procedures, and/or comments.

144. Respondent committed further departures from the standard of care in his care and treatment of Patient 7:

A. Respondent diagnosed Patient 7 with body dysmorphia without a proper evaluation - specifically, without obtaining or performing a formal psychological evaluation of Patient 7, or making a referral to a mental health professional.

B. Respondent failed to disclose to Patient 7 the frequency, or likelihood, of the complications listed in the patient's consent forms.

Patient 8

145. Patient 8, who resides outside of California, contacted Respondent's office on or about April 8, 2019, inquiring about male enhancement using a Penuma implant and scrotal implants. Patient 8 communicated with Respondent's employee, "Ray," by email and answered the following seven questions: 1) date of birth; 2) height and weight; 3) whether the patient is circumcised; 4) whether the patient uses tobacco products; 5) what medications the patient uses; 6) whether the patient had any prior penile enhancement surgeries; and 7) whether the patient has

any past or present medical condition. Based on Patient 8's answers to these questions, "Ray" informed Patient 8 that he was eligible for the procedure. Patient 8 then completed several forms about his health online, paid a deposit, and scheduled a surgery with Respondent without having ever met Respondent or having been examined by him. Patient 8 was informed by Respondent's "assistants" that "the implant is made out of the softest grade of medical silicone. The implant can bend and also has a similar texture to a gummy bear. The reaction is the result of the blood flow inside the shaft and has nothing to do with the implant. Your body also forms a capsule of tissue around the implant which gives you more of a natural feeling to the touch." Patient 8 was promised that the sensitivity of his penis would not change, because the implant was going to be under the skin, and that the procedure was "completely reversible without any downsides beside the surgery complications."

146. Respondent's records reflect no discussion of alternative options such as suspensory ligament release, or observation. The only documented plan was "subcutaneous penile implant, bilateral cup-shaped testicular implant." Even though Respondent noted that present illness is "low self-esteem/ confidence;" there was no assessment noting options besides Penuma implant, such as reassurance, therapy or medication. While Respondent had Patient 8 sign off having been offered psychological evaluation, there was no documentation that he had been offered such evaluation or had such evaluation prior to coming to Respondent's practice on the day of the operation.

147. Patient 8 travelled to California and met Respondent and was examined for the first time, on September 20, 2019. Patient 8 was presented with various forms to sign, including a "Release of Claims" and a promise "not to disclose, under any circumstances, the reasons for the removal" in consideration of a "Limited Lifetime Warranty" of the Penuma implant. On the preoperative history and physical Respondent documented that Patient 8's present illness was "low self-esteem/confidence," and a physical exam finding that Patient 8 had a tight suspensory ligament. Respondent then took Patient 8 to surgery.

148. Respondent placed the Penuma and scrotal implants in Patient 8 on September 20, 2019. On his operative report, Respondent noted that preoperative diagnosis was "tight

suspensory ligament," and that the post-procedure diagnosis was "correction of tight suspensory ligament." In his interview with the Board's investigators, Respondent stated that a tight suspensory ligament is not specifically an indication for the Penuma implant.

149. Following the procedure, Patient 8 made numerous complaints that his penis was numb. In an email to Respondent on December 7, 2019, Patient 8 complained that after he got Respondent's "green light" for sexual activity, he discovered that "there is no sensitivity at all in my penis, head and [a]long the penis." Even though Patient 8 was told that there would be no change in sensation, he was later told that there may be risk of alterations to penile sensation, and that he was the first patient to have a complete loss of sensation. Patient 8 also was told by Respondent or his "assistants" that the edges of his implant would not be felt, but the edges remained palpable and visible. Patient 8 showed this to Respondent on photographs attached to the December 7, 2019 email.

150. On or about October 14, 2019, Patient 8 consulted with Dr. Winters, with a chief complaint of pain with erections and some stitch irritation. Exam showed "thickness on the dorsum of the penis with a distinct fold near the flans on the right side. Scrotal contents are difficult to assess as part of the material wraps around the superolateral surfaces of the scrotum." "Incisions appear healthy." "As for the cosmesis, there appears to be a fold in the silicone sleeve on the right side of the penis near the dorsum." Patient 8 also saw Dr Thomas Walsh at University of Washington in December, 2019. He was noted to have glans numbness without sensation. It was noted that penile implant feels mostly symmetric, more protuberance on the right than left. On December 17, 2019, Patient 8 saw Dr Garlitz at Kaiser Permanente. On exam, he was noted to have "decreased sensation in the scrotum bilaterally. He is not able to feel pinprick sensation to the glans bilaterally and the entire shaft of the penis bilaterally down to just above the area of the penile base." The exam noted that Patient 8 "has had a loss of sensation of the distribution of the bilateral superficial dorsal penile nerves in the area of distortion of a penile nerve block."

151. Patient 8 had a virtual visit with Respondent on approximately January 22, 2020. During this virtual visit, Respondent was very defensive, reminding Patient 8 that "he signed

documents that exonerated him."

152. An MRI was done on or about January 30, 2020. It was noted that the implant appears to impinge on the region of the dorsal vein, arteries, and therefore likely the dorsal nerves, greater on the left. It assessed that his neuropraxia is most likely due to this compression.

153. In the January 30, 2020, email to Patient 8, from Respondent's practice, Patient 8 was started on Nitro-Bid, and was informed that under the terms of "Limited Lifetime Warranty," the additional anesthesia fees for implant removal surgery would be higher than were quoted to Patient 8 when he signed the release. Respondent represented to Patient 8 in an email that "During the consultation and signing of the consent forms, it was discussed that there may be a possibility of a change in the sensation of your penis. Some patients have reported an increase in sensation." This discounting of patient's reported complication was misleading, because in the case of Patient 8, placement of the Penuma implant led to nerve interruption, causing numbness and lack of sensation.

154. On or about May 5, 2020, Patient 8 underwent an operative penile exploration with a different provider, which consisted of removal of the implant, and removal of incorporated mesh, washout and drain placement for diagnosis of penile foreign body and penile pain, neuropraxia with complete loss of sensation to the distal penis. Surgical findings were: "silicone block implant placed on top of the neurovascular bundle, spanning the length of the penis. The implant was anchored to the distal phallus in the cleft of the corona directly on top of the neurovascular bundle using an approximately 2x4 cm piece of what appeared to be polypropylene mesh, which was heavily incorporated onto the neurovascular bundle and into the dartos tissue. Both the implant and the mesh were removed intact." Pathology did not show that any nerve tissue was removed.

155. On or about May 6, 2020. Patient 8, who lives outside of California, emailed Respondent's practice complaining about his complications and his dissatisfaction with Respondent's handling of those complications. Patient 8 indicated that he will complain to the Medical Board. A part of Respondent's reply was: "More importantly, you agreed that it is essential for patients to exclusively follow the instructions given by Dr. Elist's office on any

follow-up consultations, questions, communications, procedures, and/or comments. Since you chose to consult and follow your post-op care treatment with different physicians who are unfamiliar with this procedure, Dr. Elist's office cannot be held responsible or liable for any adverse events that may result."

156. Respondent committed the following extreme departures from the standard of care in his care and treatment of Patient 8:

A. During the informed consent process Respondent failed to offer Patient 8 any other available options for treatment of tight suspensory ligament.

B. Respondent offered to Patient 8 a surgical intervention that was not indicated for a tight suspensory ligament.

C. Respondent failed to truthfully disclose FDA approval status and complication profile of the Penuma implant to Patient 8.

D. Respondent sought to deter Patient 8 from seeking medical care from other providers related to the placement of the Penuma implant.

Patient 9

157. Patient 9, who resides outside of California, inquired about a penis enhancement procedure with Respondent in approximately January, 2019. He was determined to be a surgical candidate based on answering seven questions by email, and without any prior examination by a licensed medical professional. Patient 9's surgery was scheduled on or about September 24, 2019. He traveled to Respondent's office from out of state and underwent placement of Penuma implant, on or about September 24, 2019.

158. Respondent's surgical report indicated that the operation was under general anesthesia, but Respondent's certified records do not contain the surgical anesthesia record. Respondent's operative note did not indicate any complications.

159. Patient 9 returned for follow-up appointments on September 25, 26, and 27, 2019, during which no complications were noted. However, when Patient 9 returned to his state of residence, he developed swelling and seroma, which became progressively larger and more painful. Patient 9 began sending emails to Respondent's office, complaining of swelling and

seroma, beginning on October 1, 2019.

160. During November, 2019, due to increasing pain and changes in his penile skin, Patient 9 underwent seroma drainage by RN Whitney Murdock under direction of a physician. Seroma continued to return after drainage and was drained several times between November, 2019 and February, 2020.

161. On February 6, 2020, Patient 9 travelled once again to Beverly Hills to see Respondent with complaints of fluid build-up in his penis. Respondent drained Patient 9's seroma and advised of a "possible need" for a larger implant, documenting that Patient 9 was "eager to do it." Instead, Patient 9 opted for implant removal. The Penuma implant was removed by Respondent during a surgery, under general anesthesia, on February 13, 2020. The mesh in which the implant was embedded was left in place. No anesthesia record was retained. On the physical exam portion of the preoperative History and Physical form, Respondent noted "non-compliance." In his operative note of February 13, 2020, Respondent noted "After seven weeks of no email correspondence, patient reported undergoing multiple aspirations without consulting with our office, going against medical advice." This is despite the protocol of expecting patients to contact every 6-8 weeks, or every 3 months, and around 7 weeks would have been in the expected length of time.

162. After the Penuma implant was removed, Patient 9 continued to have problems that were sequalae of the incomplete implant removal surgery performed by Respondent. In May, 2020, Patient 9 saw Dr. Mark Solomon for video consultation to address the problems caused by the surgical mesh Respondent left in place following the removal of the Penuma implant. At this time, Patient 9 had 1-inch shortening and dorsal curvature of his penis. Dr Solomon completed removal of some residual mesh on June 30, 2020. Patient 9 had skin necrosis and healed secondarily, leading to eventual worsening dorsal tethering and curvature, with an hourglass deformity. While he had baseline curvature to the left, he now has worse dorsal curvature and loss of length.

163. On or about September 8, 2020, Patient 9 saw NP Brearton, complaining of 45+ degree dorsal curvature. On exam, he had multiple penile plaques, skin fixation and rigidity near

the glans penis, penile narrowing, indentations, pain, and difficulty with penetrative intercourse. A loss of three inches of penile length was noted. On or about September 19, 2020, Patient 9 saw Dr. William Brant for tethering and the nodule/lesion at midshaft. He was noted to have pain with intercourse. Per Dr. Brant's note, Dr. Brant's "primary concern is the loss of areolar tissue and tethering of the dartos to bucks fasci and the neurovascular bundle. A secondary concern is the midshaft defect which keeps ripping open with the needed traction/stretching." It was suggested that Patient 9 undergo placement of an amniotic/placental interposition graft between dartos and Buck's fascia.

164. On February 11, 2021, Patient 9 saw Dr. Brant again and eventually underwent surgery – separation of tissue, mobility, and making sure the neurovascular bundle is preserved, addressing the dorsal mass at the base, with residual concerns of nerve damage.

165. Respondent committed the following extreme departures from the standard of care in his care and treatment of Patient 9:

A. During the informed consent process, Respondent failed to offer Patient 9 any other available options for treatment of tight suspensory ligament.

B. Respondent offered to Patient 9 a surgical intervention that was not indicated for a tight suspensory ligament.

C. Respondent failed to truthfully disclose the FDA approval status and complication profile of the Penuma implant to Patient 9.

D. Respondent sought to deter patient 9 from seeking medical care from other providers related to the treatment of complications of the Penuma implant.

Patient 10

166. Patient 10, who resides outside of California, initially underwent a pre-operative history and physical examination with Respondent on or about January 4, 2021. Present illness was recorded as "states low self confidence personal image." According to the history Respondent obtained, Patient 10 had previously sought to enhance the appearance of his penis by having a liposuction surgery in his pubic area in 2020. Respondent did not elicit and/or document in his initial history that Patient 10 that Patient 10 also previously underwent a number of

BIMIX/TRIMIX injections into his corpus cavernosum. Respondent noted the history of these injections at a later date as a possible explanation of Patient 10's unsatisfactory post-surgical progress, though even then Respondent did not elicit and/or document the number, frequency or indication for those injections.

167. According to Patient 10's preoperative photos, his penile anatomy appeared to be within the norm. As noted in an article authored by Respondent, which was published in the International Journal of Impotence Research, patient selection is of the utmost importance. According to the article, which Respondent made a part of Patient 10's medical record, "Patient selection for the Penuma implant considers the patient's health status, history of the underlying issue(s) for which he seeks help, and the complexity of his particular habitus. Most importantly we seek assessment of his psychological state, particularly perceived body image distortion, including small penis anxiety and penile dysmorphic disorder (PDD), which is a variant of body dysmorphic disorder (BDD). Patients with BDD have consistently been identified as having a higher likelihood of unsatisfactory outcomes from most aesthetic surgeries." During his interview with the Board's investigators, Respondent stated that Patient 10 was flagged to be evaluated by the Center of Healthy Sex, and had undergone a psychological evaluation there. However, Respondent's records for Patient 10 contain no result of any such evaluation, and Respondent's chart for Patient 10 makes no reference whatsoever to that evaluation. Instead, Respondent's surgical consent for Patient 10 included the following, "I have been offered independent pre-surgical psychological evaluation for this procedure, and respectfully decline undergoing such evaluation." Despite these red flags, Respondent proceeded with Patient 10's surgery on January 5, 2021.

168. Among the documents Patient 10 was required to sign, Respondent included language to deter Patient 10 from seeking second opinions or medical care from other medical providers with regard to his implant: "I hereby certify that I will consult exclusively with Dr. Elist's office on any follow up consultations, questions, communications, procedures, and /or comments. Should I consult with or conduct any related procedures with any other professionals, Dr. Elist's office will not be held responsible or liable for any adverse events

(physical or psychological) that may result." "Any questions, comments, issues, support, complications, dissatisfaction due to unrealistic expectations or follow-up surgery deemed medically necessary by Dr. Elist or voluntarily desired against Dr. Elist's advice in the future, must solely be taken care of and addressed by Dr. Elist and his staff. I also acknowledge that currently, very few physicians beyond Dr. Elist have extensive knowledge of the implant procedure and the required post-operative steps. Therefore, I understand that I am encouraged to maintain contact exclusively with Dr. Elist's clinic for any questions, comments. concerns, etc. that I may have on the procedure. I understand that the clinic highly discourages seeking information elsewhere as the information provided can be false, misleading, and inaccurate. I am encouraged to pursue any and all subsequent treatments related to this implant procedure with Dr. Elist's clinic. Otherwise, James Elist, M.D. nor James J. Elist M.D. Inc. will not accept any liability or responsibility for physical or mental permanent damages incurred to the patient."

169. Patient 10 underwent penile enhancement surgery with Respondent on January 5, 2021, wherein Respondent placed a Penuma implant in Patient 10's penis. Throughout Respondent's operative notes for any of the surgeries he performed on Patient 10, all of which were based on a pre-written template, no information about the implant, such as the device serial number, implant size designation or measurements, or how much of it Respondent trimmed, was noted. Although each operative note indicated that the surgery was performed under general anesthesia, Respondent's chart for Patient 10 contained no anesthesia record.

170. Post operatively Patient 10 had persistent swelling, pain, and felt that his implant dislodged. In an email to Respondent, he provided photographs and stated that "I noticed a separation point where the implant is not joining the shaft...my penis is arching or curving as it joins the implant at the top." Respondent, through his medical assistant who was working under Respondent's supervision, reassured Patient 10 in an email : "Because you are under warranty, Dr. Elist will pay for the procedure for you. This means Dr. Elist will make an incision through the same scar you have, remove any scar tissue present, remove the implant and replace it with a larger size." However, it was not made clear why a larger size implant was even mentioned in

these communications. Patient 10 was still charged over $4,000 for the surgery center fees, "because the surgery center is independent from our office."

171. Patient 10 then underwent a revision surgery by Respondent on June 10, 2021. In his operative note, Respondent described the reason for the revision surgery, as follows:" The patient underwent the procedure of penile implant insertion, and the result of the procedure was very satisfactory. After about five months, the patient discovered he had some discomfort and bulging at the tip of the penis. This patient was seen in the office this month. Upon consultation and physician examination, it was identified that part of the suture on the lateral side had been detached due to the expansion of the penile skin." The operative report went on to state that upon surgery, "It was identified that the lateral sutures were detached." No additional detail about the failure of the sutures, or any other complications, was recorded. Respondent provided no details whatsoever about the replacement implant, such as whether it was a bigger implant as was promised to the patient or not, in his surgical report. Nor did Respondent document any information about why a removal of the old implant and replacement of it with a new implant was necessary.

172. Patient 10 continued to experience swelling, pain and feeling of dislodged implant after the first revision surgery. On June 22, 2021, Patient 10 emailed Respondent: "I think the old implant is coming apart, too lose. Extremely curved upward from the sides and it feels like it will not last a week. It occasionally stings me when I sleep on my sides. Shockingly, girth shrunk almost to my original size but the length is still half of my original length." Once again in a July 14, 2021, email, Respondent's medical assistant, supervised by Respondent, promised the patient that Respondent "will upgrade the implant."

173. Eventually, Patient 10 underwent a second revision surgery by Respondent, on July 26, 2021. Respondent's Operative Report for the July 26, 2021 operation did not mention the revision surgery on June 10, 2021. The Operative report stated: "The patient underwent the procedure of penile implant insertion, and the result of the procedure was very satisfactory. After about seven months, the patient discovered he had some discomfort and bulging at the tip of the penis. This patient was seen in the office this month. Upon consultation and physician

examination, it was identified that severe scar tissue and a seroma had formed." There was no explanation about reasons why the implant had to be removed and replaced during the second revision surgery. No information about either implant, the one removed or the replacement was recorded in Respondent's operative report or anywhere else in Respondent's chart.

174. After the second revision surgery, patient 10 continued to experience pain and dissatisfaction with the results.

175. Respondent prescribed tranexamic acid (Respondent erroneously referred to it as "tranxemic acid" (sic) in the chart) for Patient 10 to take twice daily after both of the revision surgeries. These prescriptions were referenced in Patient 10's chart on or about June 11, 2021 and July 27, 2021, during the first post-surgical follow-up in each case. Respondent did not consider and did not document consideration of his reasoning or discussion of risks and benefits of this medication. During his interview with the Board's investigators, Respondent stated that the medication was prescribed to "decrease the scar tissue and dissolve the scar tissue." "And the scar dissolves. So, you know, we had some of them, and it was given to the patient free of charge. You know, it's the same thing. Also, its – uh – like (inaudible) dissolving." However, Tranexamic acid is FDA-approved for heavy menstrual bleeding and short-term prevention in patients with hemophilia. In off-label use, it is often used in prevention of bleeding in surgical settings. It is not used for dissolving scars.

176. Respondent committed an extreme departure from the standard of care when he sought to actively deter Patient 10 from seeking medical care from other providers,

177. Respondent prescribed tranexamic acid for Patient 10 to decrease the scar tissue and/or to dissolve the scar tissue when this medication is not indicated for that purpose.

178. Respondent committed further departures from the standard of care in his care and treatment of Patient 10 as follows:

A. Respondent failed to document implant specifications in his operative reports of surgeries performed on Patient 10.

B. Respondent offered to Patient 10 a surgical intervention that was not indicated for the patient's condition.

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Patient 11

179. Patient 11, who resided outside of California, first contacted Respondent's office by filling out an on-line questionnaire on or about May 28, 2020. He was 40 years old at the time. In completing his online questionnaire, Patient 11 indicated that he was taking Lunesta (a sleeping aid), Adderall (a stimulant used to treat attention-deficit disorder), Amlodipine besylate and Losartran (both medicines for treatment of high blood pressure). Patient 11 immediately received a response email from Respondent's office with links to informational materials and, one day later, an email from a "Male Enhancement Consultant," who was working under Respondent's supervision, informing Patient 11 that based on his answers to the on-line questionnaire, he was an eligible candidate for the Penuma enhancement procedure. In his communications with Respondent's office, Patient 11 noted that the literature provided to him indicated that the success rate of the procedure was 97% or higher, and asked: "what's the number 1 cause of the procedure not being successful?" The answer was: "Most complications come from having movement or friction on the shaft from masturbation or intercourse. It is the number one cause of complications for our patients. It is very important to avoid any masturbating or intercourse for 6 weeks post surgery."

180. After exchanging several emails with Respondent's 'Male Enhancement Consultant," Patient 11 scheduled his surgery for September 25, 2020, and paid a deposit. Based on the documents he signed, a large portion of the deposit was non-refundable if the surgery was cancelled less than two weeks before the scheduled date, but Patient 11 was not examined or cleared for the surgery in time to cancel the surgery before incurring a financial penalty. He travelled to California and underwent a pre-operative physical examination and laboratory testing at providers arranged for him by Respondent, on September 24, 2020.

181. On September 25, 2020, the day of surgery, Patient 11 was examined by Respondent for the first time. Respondent, or his medical assistant, documented that the chief complaint was "desires to have penile enhancement to boost self-confidence and increase

size." During a physical examination, Respondent noted that Patient 11's penis was partially retractile and that he had a tight suspensory ligament. Patient 11 signed several consent forms, including a pre-printed acknowledgement that he was offered and independent pre-surgical psychological evaluation, and that he "respectfully" declined it. Patient 11 initialed an acknowledgement of an extensive list of possible complications, but there is no documentation that the patient was informed of the likelihood that he would suffer these complications.

182. Among the documents Patient 11 was required to sign, Respondent included language to deter Patient 11 from seeking second opinions or medical care from other medical providers with regard to his implant: "I hereby certify that I will consult exclusively with Dr. Elist's office on any follow-up consultations, questions, communications, procedures, and/or comments. Should I consult with or conduct any related, procedures with any other professionals. Dr. Elist's office will not be held responsible or liable for any adverse events (physical or psychological) that may result." "Any questions, comments, issues, support, complications, dissatisfaction due to unrealistic expectations or follow-up surgery deemed medically necessary by Dr. Elist or voluntarily desired against Dr. Elist's advice in the future, must solely be taken care of and addressed by Dr. Elist and his staff. I also acknowledge that currently, very few physicians beyond Dr. Elist have extensive knowledge on the implant procedure and the required post-operative steps. Therefore, I understand that I am encouraged to maintain contact exclusively with Dr. Elist's clinic for any questions, comments, concerns, etc. that I may have on the procedure. I understand that the clinic highly discourages seeking information elsewhere as the information provided can be false, misleading, and inaccurate. I am encouraged to pursue any and all subsequent treatments related to this implant procedure with Dr. Elist's clinic. Otherwise, James Elist, M.D. nor James J. Elist M.D. Inc. will not accept any liability or responsibility for physical or mental permanent damages incurred to the patient." Furthermore, in his post operative instructions, Respondent included the following language: "Please keep in mind that your surgeon is currently one of a few surgeons performing this type of patented penile implant surgery. We can refer you to a surgeon in

your area that performs this surgery, if available. Please therefore direct all inquiries to your surgeon's medical staff. If you consult with a medical professional untrained in this procedure, this will be against medical advice and may nullify any warranty you may have."

183. Patient 11 then underwent penile enhancement surgery with Respondent on September 25, 2020, wherein Respondent placed a Penuma implant in Patient 11's penis. Respondent's operative note for the September 25, 2020, surgery he performed on Patient 11, is based on a pre-written template, and contained nothing unique to Patient 11's surgery: it contained no information about the implant, such as the device serial number, implant size designation or measurements, or how much of the implant Respondent trimmed. The surgical note does not adequately describe how the implant was attached to Patient 11's penis, how many sutures were used or where they were placed. Although the operative note indicated that the surgery was performed under general anesthesia, Respondent's chart for Patient 11 contains no anesthesia record. The surgical note indicated that "the tight suspensory ligament was identified, and the surrounding attachments were released, and the ligament was preserved." The surrounding attachments that were "released" during the surgery are not identified and the method of their release is not described.

184. Patient 11's immediate post-surgical progress was routine, and Respondent's post-surgical note on September 29, 2020 indicted that patient 11 was prescribed tranexamic acid. However, on November 20, 2020, the patient contacted Respondent's office complaining that he could feel the edges of the implant protruding through the skin of his penis, describing that his penis had a cobra-like appearance. The response from Respondent's office was to explain that this complication was because the implant was stretching Patient 11's tight suspensory ligament, and that it would resolve with time. Starting in April 1, 2021, Patient 11 complained about persistent numbness at the top of the shaft of his penis in addition to the cobra-like appearance. In a May 7, 2021 email to Respondent, Patient 11 complained of flaring, which appears to be more pronounced in the photo that he sent Respondent. The response from Respondent's office was: "After reviewing the pictures with Dr. Elist it appears your skin has stretched and expanded and may be eligible for an upgrade. Initially your

implant was sitting on the shaft of your penis like a saddle. However, since your skin has stretched and expanded it is no longer sitting over the shaft of your penis and has begun to flatten out causing the bulges near the head of your penis." What followed were approximately two months' worth of email exchanges between Patient 11 and Respondent's office to arrange a virtual visit.

185. On July 9, 2021 Respondent finally saw Patient 11 and noted that during the Zoom call with Patient 11 the patient has implant edge flaring and that protrusion do not resolve when pulling on the head of the penis forward. The note also stated that that "his sutures may have stretched or detached due to strong nocturnal erections." Respondent recommended a revision surgery.

186. Patient 11 underwent revision surgery by Respondent on or about October 12, 2021. Despite of Respondent's "warrantee" Patient 11 was charged $3,600 to have a revision surgery, with the explanation that "the surgery center is independent from our office you will be responsible for covering the cost of the anesthesiologist, surgery center, recovery room fee..." Prior to the surgery, Patient 11 was presented with and signed a document entitled "Agreement of Payment" which provided for payment of the Surgery Center Costs and expenses. Additionally, this document provided: "Moreover, per the Consent Forms, the patient will maintain all medical communications with Dr. James J. Elist, MD's clinic or a medical professional familiar with the procedure selected at Dr. Elist's sole discretion...."

187. On October 12, 2021 Patient 11 underwent a revision surgery with Respondent that involved replacement of Patient 11's penile implant. In his operative report Respondent deflected the failure of the original surgery on Patient 11, describing reason for the surgery as follows: "Upon consultation and physician examination, it was identified that part of the suture on the lateral side had been stretched due to the rough movement of the penis." Respondent's operative report went on to note that "it was identified that the lateral sutures were stretched. The implant was pulled out of the incising and was intact." The intact implant that was removed from Patient 11's penis was replaced with a new implant, but Respondent's operative report was based on a previously written template and contained

minimal information pertinent to the surgery. Respondent's operative report did not describe the difference between the implant that was removed and the implant that replaced it, and did not explain why it was necessary to replace the previous implant when it was intact and the problem was not with the implant, but with "stretched sutures."

188. On October 16, 2011, Patient 11 was seen for post-surgical follow-up. Respondent's note indicated that Patient 11 was to be prescribed Zafirlukast 20 mg 1 PO BID #60 for 3 months with 2 refills and Tranexamic acid 2 PP BID #30 for one week. Post-operatively, Patient 11 continued to deal with swelling and pain that kept him from sleeping. On December 5, 2021 patient emailed Respondent and explained that there was pronounced ridge on the left of his penis. Also noted that penis has taken on an S-shape with extra skin appearing nearing bottom of the head, as well as significant retraction. To this, Dr Elist's practice responded that "This is due to the length of the implant which was inserted and tight suspensory ligament which is causing your penis to retract. As the implant continues to stretch out the ligament your penis will straighten and drop leading to the lengthening/elongation process." This explanation was despite the fact that Patient 11's "tight suspensory ligament" was being stretched by the original implant for over a year, and during Patient 11's pre-operative physical examination before the revision surgery on October 12, 2020, Respondent noted that Patient 11 did not have a tight suspensory ligament. There was no resolution of these issues according to medical records provided by Respondent. Patient 11 had sought subsequent care from other providers, including removal of the implant, but he continues to suffer from adverse sequala of surgeries Respondent's operations.

189. Respondent committed an extreme departure from the standard of care when he sought to deter patient 11 from seeking medical care from other providers related to the treatment of complications of the Penuma implant.

190. Respondent committed an extreme departure from the standard of care when he failed to document any implant specifications, or the size adjustments to the implants that he made during surgery in his operative reports regarding Patient 11.

191. Respondent committed an extreme departure from the standard of care when he prescribed tranexamic acid and Zafirlukast for Patient 11 without disclosing to patient 11 that these medications were being used "off-label."

192. Respondent committed the following further departures from the standard of care in his care and treatment of Patient 11:

A. In providing informed consent information to Patient 11, Respondent did not discuss the likelihood of various possible complication with Patient 11.

Patient 12

193. Patient 12 completed a "New Patient intake Form" for Respondent's practice on March 29, 2018. Patient 12 sought to surgically enhance the size of his penis. Respondent's intake form and other documents associated with his practice indicated that Respondent was a "Diplomate National Board of Urology." In his interview with the Board investigators, Respondent confirmed that he is certified by the National Board, which is officially named "The National Board of Physicians and Surgeons." "National Board of Urology" is not an official organization but bears enough resemblance to the American Board of Urology that can easily mislead patients into believing that Respondent is a "Board Certified Urologist."

194. On April 10, 2018, Respondent's staff documented that Respondent "does not think that [Patient 12] will be a candidate for the implant but the patient does want to try." In his interview, Respondent noted that this was because Patient 12 had a history of fat grafting to his penis. Respondent's pre-operative examination did not elicit and did not document the details of Patient 12's prior penile enhancement treatment.

195. On or about May 11, 2018, and prior to other surgeries that Respondent performed on patient 12, the patient was asked to sign documents that sought to deter Patient 12 from seeking medical care, related to complications or follow up of Respondent's care, from other medical providers. The documents contained the following language: "I hereby certify that I will consult exclusively with Dr Elist's office on any follow-up consultations, questions, communications, procedures, and/or comments. Should I consult with or conduct any related procedures with any other professionals, Dr Elist's office will not be held responsible or liable for

any adverse events (physical or psychological) that may result." "Any questions, comments, issues, support, complications, dissatisfaction due to unrealistic expectations or follow-up surgery deemed medically necessary by Dr Elist or voluntarily desired against Dr Elist's advice in the future, must solely be taken care of and addressed by Dr Elist and his staff. Otherwise, James Elist, MD nor James J Elist MD Inc not accept any liability or responsibility for physical or mental permanent damages incurred to the patient." "By signing below, I agree to keep in the strictest confidence and not to disclose, under any circumstances, all aspects my relationship with Dr James J Elist, James J Elist MD, a California Medical Corporation and/or all of their past, present professional corporations, partnership, agents, servants, employees, partners, directors, shareholders, assistants or physicians selected by them an all other persons (collectively, the 'Elist Parties'), including, without limitations, relating to the CONDITIONS, PROCEDURES AND THE EFFECTS thereof. I further agree that in the event I breach this confidentiality provisions, the Elist Parties shall have the right to injunctive relief, in addition to the other remedies available to them, to enforce such provision."

196. On May 11, 2018, Patient 12 underwent removal of fat injection, scar tissue and adhesions by Respondent. In his operative note, Respondent wrote that "it was identified that the patient had underwent previous penile augmentation procedures specifically penile fat injections and suspensory ligament release. Additionally, it was identified that patient had formed possible adhesions and scar tissue which would need to be removed prior to the insertion of the subcutaneous penile implant. Patient was informed that insertion of the subcutaneous penile implant is dependent on the presence of adequate skin to safely accommodate the implant." Respondent further noted that "large fat nodules and severe scar tissue were removed. It was determined that the amount of healthy skin and space was insufficient to insert the subcutaneous penile implant." Respondent's operative note did not identify where the scar tissue was removed from or how much was removed.

197. After Patient 12 recovered from the May 11, 2018 surgery, Respondent operated on him again, and inserted a Penuma implant into his penis, on or about February 7, 2019. Respondent's operative note for the February 7, 2019, surgery he performed on Patient 12, is

based on a pre-written template, and contained nothing unique to Patient 12's surgery: it contained no information about the implant, such as the device serial number, implant size designation or measurements, or how much of the implant Respondent trimmed. The surgical note does not adequately describe how the implant was attached to Patient 12's penis, how many sutures were used or where they were placed. Although the operative note indicated that the surgery was performed under general anesthesia, Respondent's chart for Patient 12 contains no anesthesia record.

198. On the first day following surgery, February 8, 2019, Patient 12 returned to Respondent's office with a large amount of swelling in his penis, scrotum and incisional line, as well as a small amount of bleeding in the area of incision. Respondent operated on Patient 12 on that date to evacuate the hematoma. In his procedure note, Respondent only described that Patient 12 had "complaints of discomfort and pain in the suprapubic area and penis." According to his procedure note, Respondent re-opened the incision, evacuated a hematoma, and applied cautery, though Respondent's procedure note only described the hematoma as "large" and gave no location, volume or description of the material evacuated, or the location or reason for the bleeding.

199. According to Patient 12's chart notes, On February 18, 2019, Patient 12 was informed that the implant might have to be removed if "it's not sitting well and perforating" and that "the patient was reminded the higher risk was dissed with him in advance of the procedure." On March 7, 2019, it was noted that there was superficial erosion of the patient's skin "in some areas" and that "Patient expressed that he is happy with the result and that Dr. Elist informed him that he will do everything to try and save his implant." Starting on approximately June 7, 2019, email communications between Respondent's office and Patient 12 were indicative of an infection.

200. On July 22, 2019, Patient 12 underwent another surgery by Respondent to remove his subcutaneous penile implant. Respondent's operative report for that procedure is inaccurate in several aspects. Respondent wrote that the removal of the implant was due to "swelling, inflammation, discomfort and erosion on the penis" but omitted any mention of the

infection. Respondent inaccurately recounted Patient 12's prior history, writing that previous evacuation of the hematoma performed was "after about a month" of placement of the Penuma implant, when in fact evacuation of the hematoma occurred on the very next day. Respondent indicated that "upon physical examination, the patient was found to have severe scar tissue formation secondary to dermal graft and fat injection, seroma formation and erosion on his penile skin." In prior operative notes, removal of or presence of a dermal graft was never mentioned, and no details or the location of any of the complications that led to the removal of the implant on July 22, 2019 was documented.

201. Post operatively, Patient 12 continued to experience sequala, including scarring, decreased sensation, according to Patient 12's email to Respondent on February 21, 2020, and loss of penile length, according to an email on April 21, 2020. Subsequent treating physician also documented scar tissue in the suprapubic area and hourglass appearance at the base of Patient 12's penis and scar tissue extending on the dorsal aspect of the penis all the way to the corona, in February, 2020.

202. Respondent committed an extreme departure from the standard of care when he performed an unnecessary surgery to remove previously grafted fat on May 11, 2018 from Patient 12.

203. Respondent committed an extreme departure from the standard of care when he sought to deter patient 12 from seeking medical care from other providers related to the treatment of complications of the Penuma implant.

204. Respondent committed an extreme departure from the standard of care when he failed to document any implant specifications, or the size adjustments to the implant that he made during surgery in his operative reports regarding Patient 12.

205. Respondent committed the following departures from the standard of care in his care and treatment of Patient 12:

A. In providing informed consent information to Patient 12, Respondent did not discuss the likelihood of various possible complication with Patient 12 given his prior surgical history.

B. Respondent's intake paperwork indicated that he is a "Diplomate National board of Urology" which is deceptive, because the National Board does not constitute an official board certification in Urology which is provided by the American Board of Urology.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

206. Respondent James Jamshid Elist, M.D. is subject to disciplinary action under section 2234, subdivision (b), of the Code, in that he committed gross negligence in his care and treatment of Patients 1, 2, 7, 8, 9, 10, 11 and 12. The circumstances are as follows:

207. Allegations set forth in paragraphs 7 through 41, 42 through 57, 59 through 69, 131 through 143, 145 through 156, 157 through 165, 166 through 177, 179 through 191, and 193 through 204 are incorporated herein by reference as if fully set forth.

208. Respondent's acts and/or omissions as set forth in paragraph 207, whether proven individually, jointly, or in any combination thereof, constitute gross negligence pursuant to section 2234, subdivision (b), of the Code. As such, cause for discipline exists.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

209. Respondent is subject to disciplinary action under section 2234, subdivision (c), of the Code in that he committed repeated negligent acts in his care and treatment of Patients 1, 2, 3, 4, 5,6, 7, 8, 9, 10, 11, and 12. The circumstances are as follows:

210. The allegations set forth in paragraphs 7 through 205 herein are incorporated by reference as if fully set forth.

211. Respondent's acts and/or omissions as set forth in paragraphs 7 through 205 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute repeated negligent acts pursuant to section 2234, subdivision (c), of the Code. As such, cause for discipline exists.

THIRD CAUSE FOR DISCIPLINE

(Incompetence)

212. Respondent is subject to disciplinary action under section 2234, subdivision (d), of

the Code, in that he demonstrated incompetence in his care and treatment of Patients 1, 2, 3, 4, 5, and 6. The circumstances are as follows:

213. The allegations set forth in paragraphs 7 through 130 herein are incorporated by reference as if fully set forth.

214. Respondent's acts and/or omissions as set forth in paragraphs 7 through 130, inclusive above, whether proven individually, jointly, or in any combination thereof, amount to incompetence in violation of Code section 2234, subdivision (d). As such, cause for discipline exists.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Medical Records)

215. Respondent is subject to disciplinary action under section 2266 of the Code, in that he failed to maintain adequate and accurate records relating to the provision of services to Patients 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12. The circumstances are as follows:

216. The allegations set forth in paragraphs 7 through 205 herein are incorporated by reference as if fully set forth.

217. Respondent's acts and/or omissions as set forth in paragraphs 7 through 205, inclusive above, whether proven individually, jointly, or in any combination thereof, represent the failure to maintain adequate and accurate records in violation of Code section 2266. As such, cause for discipline exists.

DISCIPLINARY CONSIDERATIONS

218. To determine the degree of discipline, if any, to be imposed on Respondent James Jamshid Elist, M.D., Complainant alleges that on or about August 16, 2019, in a prior disciplinary action entitled *In the Matter of the Accusation Against: Jamshid Elist, M.D.*, before the Medical Board of California, in Case Number 800-2015-016513, Respondent's license was publicly reprimanded for "fail[ing] to maintain adequate and accurate medical records in [the care and treatment of a patient], in violation of Business and Professions Code section 2266, as more fully described in the Second Cause for Discipline set forth in Accusation No. 800-2015-016513."

Respondent was also ordered to take a medical record keeping course. That decision is now final and is incorporated by reference as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number A 35400, issued to Respondent James Jamshid Elist, M.D.;

2. Revoking, suspending or denying approval of Respondent James Jamshid Elist, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent James Jamshid Elist, M.D., to pay the Board the costs of the investigation and enforcement of this case, and if placed on probation, the costs of probation monitoring; and

4. Taking such other and further action as deemed necessary and proper.

DATED: AUG 04 2023

JENNA JONES FOR
REJI VARGHESE
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California

Complainant